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10/576,938	08/23/2006	Stephane Chevallier	13415/104015	9914

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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,938	CHEVALLIER, STEPHANE	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,17 and 19-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,17 and 19-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glenord Pty. Ltd. (WO 02/072182). Glenord discloses the device substantially as claimed including a safe injection device (Figs. 1-6) comprising a syringe having a syringe body (12) , a needle (16) , and a piston suitable for moving in the body to perform an injection (34), and a protective sheath (10/11), the syringe body and the protective sheath being suitable for sliding relative to each other (Figs. 1 and 5) between an injection configuration in which the needle projects beyond the protective sheath (Fig. 1) which is disposed around the syringe body, and a protection configuration in which the needle extends inside said sheath (Fig. 5), the device

including a trigger member (30) suitable for causing the device to pass from the injection configuration (Fig. 1) to the protection configuration at the end of the injection stroke (Fig. 5), the trigger member being secured to an actuator head of the piston (30 is secured to the piston and can be considered being connected to an actuator head as this portion helps to actuate the injection as well as other portions of the piston), the device comprising an inhibitor member (23/36/37) suitable for occupying an inhibit position in which said inhibitor member defines a first end-of-injection-stroke position for the piston in which the trigger member is unable to cause the device to pass from the injection configuration to the protection configuration (Fig. 2), and the inhibitor member is suitable for being moved from said inhibit position to enable the piston to reach a second end-of-injection-stroke position in which the trigger member is able to cause the device to pass from the injection configuration to the protection configuration (Figs. 3 and 4 disclose that the inhibitor member may be moved out of the way of completion of the injection stroke and allows completion as seen in Fig. 5), wherein in the inhibit position, the inhibitor member is connected to the actuator head of the piston (Fig. 2a shows that 23 is connected to the indented portion of the piston preventing completion of the injection), being constrained to move therewith and is suitable for co-operating in abutment with an element of the device that is stationary relative to the syringe body (19) to define the first end-of-injection-stroke position, and the inhibitor member is suitable for being separated from the piston to enable the second end-of- injection-stroke position to be reached (Figs. 3 and 4 show separation of the inhibitor member and Fig. 5 shows the end of injection stroke being reached), such that in the inhibition

position, the user presses the inhibit member to advance the piston (the user must move the inhibit member such that the piston can be advanced. While the inhibit member must be moved outwardly, since Applicant does not claim that the inhibit member must be pressed in the distal direction, it is the examiner's position that it can be interpreted that the user moving the inhibitor member outwardly can be interpreted as pressing the inhibitor member outwardly, and this allows the piston to be advanced. Please note that the claim language is currently part of a "wherein" clause and that the Glenord device is capable of meeting this functional language as indicated above), and when the inhibit member is separated from the piston the user presses the actuator head of the piston to advance the piston (the user presses the actuator head to advance the piston). While Glenord discloses that the inhibitor member (23/36/37) is formed by a tenon or by a wall element on the outside of the piston head (Fig. 1 for example), Glenord does not disclose that the inhibitor member passes through the head of the piston. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Glenord such that the inhibitor member was moved from the outside of the head of the piston, to be placed on the inside of the head of the piston, as it has been held that mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

In reference to claim 32, Glenord discloses that the user presses on the inhibitor member while in the inhibit position, and when the inhibitor member is separated or displaced with regard to the piston, the user presses on the head of the piston (Figs. 1 and 5).

Claims 17 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glenord Pty. Ltd. (WO 02/072182). Glenord discloses the device substantially as claimed including a safe injection device (Figs. 1-5) comprising a syringe having a syringe body (12), a needle (16), and a piston (22) suitable for moving in the body to perform an injection, and a protective sheath (10/11), the syringe body and the protective sheath being suitable for sliding relative to each other between an injection configuration (Fig. 1) in which the needle projects beyond the protective sheath which is disposed around the syringe body, and a protection configuration in which the needle extends inside said sheath (fig. 5), the device including a trigger member (30) suitable for causing the device to pass from the injection configuration to the protection configuration at the end of the injection (30 acts on portions 25 and 29 to release the syringe) stroke, the trigger member being secured to an actuator head of the piston (30 is secured to the piston and can be considered being connected to an actuator head as this portion helps to actuate the injection as well as other portions of the piston), the device comprising an inhibitor member (23/36/37) suitable for occupying an inhibit position in which said inhibitor member defines a first end-of-injection-stroke position for the piston in which the trigger member is unable to cause the device to pass from the injection configuration to the protection configuration (Fig. 1, inhibitor contacts 19 and prevents completion of the injection), and the inhibitor member is suitable for being moved from said inhibit position to enable the piston to reach a second end-of-injection-stroke position in which the trigger member is able to cause the device to pass from the

injection configuration to the protection configuration (Figs. 3 and 4 disclose that the inhibitor is moved out of the way and allows the injection to be completed in Fig. 5), wherein in the inhibit position, the inhibitor member is connected to the actuator head of the piston (Fig. 1), being constrained to move therewith and is suitable for co-operating in abutment with an element of the device that is stationary relative to the syringe body (19) to define the first end-of-injection-stroke position (Fig. 2), and the inhibitor member is suitable for being displaced relative to the piston to enable the second end of-injection-stroke position to be reached (Figs. 3 and 4 disclose the inhibitor being displaced and allowing the end of injection stroke to be reached in Fig. 5). such that in the inhibition position, the user presses the inhibit member to advance the piston (the user must move the inhibit member such that the piston can be advanced. While the inhibit member must be moved outwardly, since Applicant does not claim that the inhibit member must be pressed in the distal direction, it is the examiner's position that it can be interpreted that the user moving the inhibitor member outwardly can be interpreted as pressing the inhibitor member outwardly, and this allows the piston to be advanced. Please note that the claim language is currently part of a "wherein" clause and that the Glenord device is capable of meeting this functional language as indicated above), and when the inhibit member is separated from the piston the user presses the actuator head of the piston to advance the piston (the user presses the actuator head to advance the piston). While Glenord discloses that the inhibitor member (23/36/37) is formed by a tenon or by a wall element on the outside of the piston head (Fig. 1 for example), Glenord does not disclose that the inhibitor member passes through the head of the

piston. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Glenord such that the inhibitor member was moved from the outside of the head of the piston, to be placed on the inside of the head of the piston, as it has been held that mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

In reference to claim 33, Glenord discloses that the user presses on the inhibitor member while in the inhibit position, and when the inhibitor member is separated or displaced with regard to the piston, the user presses on the head of the piston (Figs. 1 and 5).

Claims 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glenord Pty. Ltd. (WO 02/072182). Glenord discloses the device substantially as claimed including a safe injection device (Figs. 1-5) comprising a syringe having a syringe body (12), a needle (16), and a piston suitable for moving in the body to perform an injection (22), and a protective sheath (10/11), the syringe body and the protective sheath being suitable for sliding relative to each other between an injection configuration in which the needle projects beyond the protective sheath which is disposed around the syringe body (Fig. 1), and a protection configuration in which the needle extends inside said sheath (Fig. 5), the device including a trigger member (23/36/37) suitable for causing the device to pass from the injection configuration to the protection configuration at the end of the injection stroke (Fig. 5), the device including

means for defining a first end-of-injection-stroke situation in which the trigger member is unable to cause the device to pass from the injection configuration to the protection configuration (Fig. 2), and a second end-of- injection-stroke situation in which the trigger member is able to cause the device to pass from the injection configuration to the protection configuration (Figs. 3-5), the trigger member being constrained to move with the piston (Figs. 1-4), and said first and second end-of- injection-stroke situations corresponding respectively to first and second end-of- injection-stroke positions for the piston, the device including a housing in which a head of the piston is substantially retracted in the second end-of-injection-stroke position, whereas, in the first end-of-injection-stroke position, the piston head projects beyond said housing to provide a purchase enabling the piston to be pulled away from the needle (Fig. 5). such that in the inhibition position, the user presses the inhibit member to advance the piston (the user must move the inhibit member such that the piston can be advanced. While the inhibit member must be moved outwardly, since Applicant does not claim that the inhibit member must be pressed in the distal direction, it is the examiner's position that it can be interpreted that the user moving the inhibitor member outwardly can be interpreted as pressing the inhibitor member outwardly, and this allows the piston to be advanced. Please note that the claim language is currently part of a "wherein" clause and that the Glenord device is capable of meeting this functional language as indicated above), and when the inhibit member is separated from the piston the user presses the actuator head of the piston to advance the piston (the user presses the actuator head to advance the piston). While Glenord discloses that the inhibitor member (23/36/37) is formed by a

tenon or by a wall element on the outside of the piston head (Fig. 1 for example), Glenord does not disclose that the inhibitor member passes through the head of the piston. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Glenord such that the inhibitor member was moved from the outside of the head of the piston, to be placed on the inside of the head of the piston, as it has been held that mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

In reference to claim 20, Glenord discloses an inhibitor member suitable for occupying an inhibit position in which the end-of-injection-stroke situation is said first situation, and suitable for being moved relative to said inhibit position to enable the end-of-injection-stroke situation to be said second situation (Figs. 2-5).

In reference to claim 21, Glenord discloses abutment means (abutment between 19 and 23/36/37) suitable for being put into operation to define the first end-of-injection-stroke position and for being taken out of operation to enable the second end-of-injection-stroke position to be reached (Figs. 2-5).

In reference to claim 22, Glenord discloses wherein in the inhibit position, the inhibitor member is connected to the piston being constrained to move therewith, and is suitable for co-operating in abutment with an element of the device that is stationary relative to the syringe body in order to define the first end-of-injection- stroke position (Figs. 3-4).

In reference to claim 23, Glenord discloses the inhibitor member is suitable for being separated from the piston, in order to enable the second end-of- injection-stroke position to be reached (Figs. 3-5).

In reference to claim 24, Glenord discloses that the inhibitor member is suitable for being displaced relative to the piston, in order to enable the second end- of-injection-stroke position to be reached (Figs. 3-5).

In reference to claim 25, Glenord discloses that the trigger member is secured to the actuator head of the piston, and the inhibitor member is connected to said head in the inhibit position (Figs. 3-4).

In reference to claim 26, Glenord discloses that in the inhibit position, the inhibitor member passes through the head of the piston (Figs. 1 and 2).

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glenord Pty. Ltd. (WO 02/072182). Glenord discloses a safe injection device (Figs. 1-5) comprising a syringe having a syringe body (12), a needle (16), and a piston suitable for moving in the body to perform an injection (22), and a protective sheath (10/11), the syringe body and the protective sheath being suitable for sliding relative to each other between an injection configuration in which the needle projects beyond the protective sheath which is disposed around the syringe body (Fig. 1), and a protection configuration in which the needle extends inside said sheath (Fig. 5), the device

including a trigger member suitable for causing the device to pass from the injection configuration to the protection configuration at the end of the injection stroke (30), the trigger member being formed by a skirt secured to the piston head (30), the device including an inhibitor member formed by a part (23/36/37) that, in an inhibit position, is fitted on the head of the piston and presents an end suitable for coming into abutment against an element (19) that is stationary relative to the syringe body in order to define a first end-of-injection-stroke position for the piston in which the skirt is unable to cause the device to pass from the injection configuration to the protection configuration (fig. 2), and that is suitable for being separated from the head of the piston in order to enable a second end-of-injection-stroke position of the piston to be reached in which the skirt is able to cause the device to pass from the injection configuration to the protection configuration (Figs. 3 and 4 disclose the inhibitor member being separated from the piston head and thus allowing the end of the injection stroke in Fig. 5). such that in the inhibition position, the user presses the inhibit member to advance the piston (the user must move the inhibit member such that the piston can be advanced. While the inhibit member must be moved outwardly, since Applicant does not claim that the inhibit member must be pressed in the distal direction, it is the examiner's position that it can be interpreted that the user moving the inhibitor member outwardly can be interpreted as pressing the inhibitor member outwardly, and this allows the piston to be advanced. Please note that the claim language is currently part of a "wherein" clause and that the Glenord device is capable of meeting this functional language as indicated above), and when the inhibit member is separated from the piston the user presses the actuator

head of the piston to advance the piston (the user presses the actuator head to advance the piston). While Glenord discloses that the inhibitor member (23/36/37) is formed by a tenon or by a wall element on the outside of the piston head (Fig. 1 for example), Glenord does not disclose that the inhibitor member passes through the head of the piston. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Glenord such that the inhibitor member was moved from the outside of the head of the piston, to be placed on the inside of the head of the piston, as it has been held that mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

In reference to claim 28, Glenord discloses that in the inhibit position, the inhibitor member passes through the head of the piston (Figs. 1 and 2).

Response to Arguments

Applicant's arguments filed 10/15/2009 have been fully considered but they are not persuasive. As indicated in the rejection above, since Applicant has not claimed which direction the inhibition member must be pressed, it is the examiner's position that the user presses the inhibition member away from the syringe barrel (outwardly) to advance the plunger. Since Applicant has not claimed directionality or further structure, it is the examiner's position that Glenrod can still be used as a reference against the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
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